Remarks

The Office Action mailed May 10, 2007 has been received and reviewed. Claims 1, 18, 32, and 50 have been amended. Claims 14, 15, 29, 46, 47, 64, and 65 were previously canceled, without prejudice. Pending claims are claims 1-13, 16-28, 30-45, 48-63, 66, and 67. Reconsideration and withdrawal of the rejections are respectfully requested.

Amendments to the Claims

Claims 1, 32, and 50 have been amended to indicate that the claimed devices "have materials distributed in one or more separate insertable agent delivery devices contained within the lumen of said shunt, wherein said agent delivery device(s) is selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof."

Claim 18 was similarly amended for the claimed cannula, wherein the cannula can "have materials distributed in one or more separate insertable agent delivery devices contained within the lumen of said cannula, wherein said agent delivery device(s) is selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof."

The amendments are fully supported by Applicants' disclosure. Support for claiming an insertable agent delivery devices contained within the lumen of either a shunt (Claims 1, 32, or 50) or a cannula (Claim 18) can be found in Fig. 5, Fig. 6, and Fig. 7 and described on page 10, first paragraph, page 11, describing Figure 5, pages 11-12, describing Fig. 6, and page 12, second paragraph.

No new matter is introduced by the amendments.

The 35 U.S.C. § 103 Rejections

Burnett in view of Wu

The Examiner rejected claims 1, 2, 11-12, 13, 16-19, 23, 28, 30-33, 37, 42-45, 48-51, 55, 60-63, 66, and 67 under 35 U.S.C. §103(a) as being unpatentable over Burnett (U.S. Patent No. in view of Wu (US6,656,506). Of the rejected claims, claims 1, 18, 32, and 50 are independent.

The Examiner has cited Burnett for disclosing the apparatus as claimed by the Applicant, with regard to claims 1, 18, 32, and 50 (the independent claims of Applicant). Burnett has been cited by the Examiner for disclosing an implantable fluid management system that may be implanted within a patient comprising an elongated conduit or cannula or tube 11 with a lumen therethrough, a proximal end with at least one opening or a plurality of perforations at the intake end (column 3, lines 10-20). The tube comprises an outflow end that discharges bodily fluids to another location within the body (generally, columns 1-2, Figure 16C). The conduit is cited for comprising one or more occlusion-resistant materials that may be integrated within or coated upon the surfaces of the system, which include the lumen of the tube (column 7, lines 38-65).

The Examiner points out that Burnett fails to disclose that the occlusion resistant materials are distributed in separate agent delivery devices selected from the group comprising spheres, plugs, seeds, rods, or combinations thereof. The Examiner uses Wu for teaching the agent delivery that incorporates polymer-based drug eluting microparticles of various shapes (including spheres).

The Examiner has stated clearly that the conduit is cited for comprising one or more occlusion-resistant materials that may be **integrated within or coated upon** the surfaces of the

system, which include the lumen of the tube (column 7, lines 38-65).

Applicant's previous amendment included changes to clearly distinguish over Burnett. Independent Claims 1, 32, and 50 have been amended to indicate that the claimed devices "have materials distributed in one or more **separate** agent delivery devices **contained within the lumen of said shunt**." It does not seem possible that coatings to the wall of devices taught by Burnett can also be read to include devices separately contained within the lumen as separate agent delivery devices. The materials of Burnett require the outer wall of the tube for support, and hence can not be contained within the lumen. Burnett treats the existing walls with agents which are then integrated within or coated on the surface. Applicants believe the Examiner has taken a strained interpretation of the plain meaning of the words of the claim to interpret Burnett has having taught separate agent delivery devices within the lumen of the device. Applicants understand that through the teaching of Burnet a new device is formed, but respectively disagree that Burnet teaches one or more separate agent delivery devices contained within the lumen of the shunt.

However, to forward Examination, Applicants have amended independent Claims 1, 18, 32, and 50 to specifically indicate the separate insertable agent delivery device. In the Examiner comments to the previously submitted claims the Examiner indicated that "In response to applicant's argument that the references fail to show certain features of applicant's invention (such as an agent delivery device inserted within the lumen of the claimed cannula), it is noted that the features upon which applicant relies (i.e., agent delivery devices inserted within the cannula) are not recited in the claims(s). In order to make that explicit applicants have amended the claims to indicate a separate insertable agent delivery device. No where does Burnett teach a separate insertable agent device within the lumen of the canula or shunt.

In regard to the teachings of Wu, Wu's teaching is related to drug-loaded microparticles that can be incorporated onto the surface of a medical device. The drug coated microspheres are applied onto a medical device by dipping the device into a polymer matrix so that a coating of the polymer matrix has a relatively smooth surface texture over the entire surface. Alternatively, Wu teaches the medical device can be spray coated with a polymer matrix. Coating a medical device by either method with a polymer matrix does not lead or render obvious Applicants Invention of having one or more separate agent delivery devices contained within the lumen of the shunt or cannula, nor are such devices insertable. Applicants contend that Wu's reference to a microsphere or nanosphere is related to drug particles contained within a coating. Spheres of the present invention are agent delivery devices separately contained and insertable within the lumen of device. Applicants content there spheres can not be equated with having microspheres or nanospheres coated onto the inner or outer surface of the device. Applicants draw the attention of the Examiner to Figures 2-13 of their specification where the separate insertable agent delivery devices contained within the lumen of the device can not be confused with being a coated microsphere or nanosphere on the wall of the shunt or cannula.

In view of the submitted amendments, and arguments presented above, Applicants respectively request the present rejection over Burnett in view of Wu be removed.

Claims 3-5, 20-22, 34-36, 52-54 Rejection over Burnett in view of Wu, further in View of Kraus

Claims 3-5, 20-22, 34-36, and 52-54 were rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,195,608 to Burnett in view of US 6,656,506 to Wu et al, further in view of US 5,928,128 to Kraus.

The Examiner indicates that in the specification and figures, the prior art suggests the apparatus substantially as claimed by Applicant with the exception of the composition of the implantable shunt. The Examiner has cited the Kraus reference for disclosing a shunt comprising a conduit with inflow and outflow ends (Fig. 6A) that comprises a valve to control fluid flow and that may be made of silicone or polyurethane in order to enhance biocompatibility (column 3, lines 15-30; column 6, lines 45-57).

Applicants acknowledge Kraus teaches a conduit with a valve to control fluid flow that may be made of silicone or polyurethane. However, the addition of Kraus does not cure the problem. Neither reference, alone nor in combination, teach devices having materials distributed in one or more separate insertable agent delivery devices contained within the lumen of said shunt (see arguments presented above to Burnett in view Wu).

In view that Burnet in view of Wu in further view of Kraus do not teach one or more separate agent delivery devices contained within the lumen of a shunt or cannula, Applicants respectively request the present rejection removed.

Claims 7-10, 24-27, 38-41, and 56-59 under 35 U.S.C. 103(a) over Burnett inv view of Wu et al, further in view of Hunter

Claims 7-10, 24-27, 38-41, and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,195,608 to Burnett in view of US 6,656,50 to Wu et al, further in view of US 2005/0208095 A1 to Hunter et al.

The Examiner has indicated that in the specification and figures, the prior art suggests the device and method substantially claimed by Applicant with the exception of incorporating myocphenolic acid as a therapeutic agent within the shunt. Specifically, with regard to claims 7, 8, 9, 24-26, 38-40, and 56-58, the Examiner contents that Hunter discloses a method of treating patients with various conditions by providing an implantable medical device comprising a therapeutic agent into a patient and allowing the therapeutic agent to elute into the patient (see para. 0014). In one embodiment, the therapeutic material may comprise mycophenolic acid in order to inhibit fibrosis (para. 0223). The Examiner has indicated that it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design (see MPEP 2144.07). The Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt suggested by the prior art with the therapeutic agent disclosed by Hunter in order to provide the desired therapeutic result and inhibit fibrosis, as taught by Hunter.

With regard to Applicant's claims 10, 27, 41, and 59, drawn to a "combination" of mycophenolic acid and another agent, the Examiner indicates the claims fail to specify the amounts of the combination. As indicated the Examiner points out that a mixture of 100% mycophenolic acid and 0% other agents may comprise a combination, giving the term "combination" its broadest interpretation.

Applicants acknowledge Hunter teaches a method of treating patients with various conditions by providing an implantable medical device that allows the therapeutic agent to elute into the patient, wherein the therapeutic material may comprise mycophenolic acid to inhibit fibrosis. However, the addition of Hunter does not cure the problem of Burnett or Wu, or those references in combination. Neither reference, nor in combination, teach devices having materials

distributed in one or more separate insertable agent delivery devices contained within the lumen of said shunt (see arguments presented above to Burnett in view of Kraus).

In view that Burnet in view of Wu in further view of Kraus do not teach one or more separate agent delivery devices contained within the lumen of a shunt or cannula, Applicants respectively request the present rejection removed.

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby. It is respectfully requested that should the Examiner still have questions about the allowability of the subject claims that Applicants representative meet with the Examiner to discuss any remaining issues.

Respectfully submitted for,
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Date

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